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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/723,795	11/26/2003	Claudiu Supuran	MST-2393 U.S.	9070
24988	7590	01/02/2008		
LEONA L. LAUDER 235 MONTGOMERY STREET, SUITE 1026 SAN FRANCISCO, CA 94104-0332			EXAMINER FETTEROLF, BRANDON J	
			ART UNIT	PAPER NUMBER
			1642	
			NOTIFICATION DATE	DELIVERY MODE
			01/02/2008	ELECTRONIC

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

deeopat@pacbell.net  
LLLpat@pacbell.net  
jharland@pacbell.net

<b>Office Action Summary</b>	<b>Application No.</b> 10/723,795	<b>Applicant(s)</b> SUPURAN ET AL.	
	<b>Examiner</b> Brandon J. Fetterolf, PhD	<b>Art Unit</b> 1642	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 07 November 2007.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 67-70, 72-75 and 77-90 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 67-70, 72-75 and 77-90 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |   |   |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)  | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date <u>11/07/2007</u> . | 6) <input type="checkbox"/> Other: _____  |

### DETAILED ACTION

Applicant's request for reconsideration of the finality of the rejection of the last Office action is persuasive and, therefore, the finality of that action is withdrawn.

Claims 67-70, 72-75 and 77-90 are currently pending and under consideration.

#### Rejections Withdrawn:

The rejection of Claims 67-70, 72-84 and claims 85-90 under 35 U.S.C. 112, first paragraph, enablement, is withdrawn in view of Applicants arguments. In particular, Applicants arguments and evidence presented in Svastova et al., FEBS Lett., 577:439-445 (2004), Cecchi et al., J Med\_ Chem., 48:4834-4841 (2005), and Alterio et al., J Am. Chem. Soc., 128:8329-8335 (2006).

#### New Rejections upon further consideration:

##### *Claim Rejections - 35 USC § 112*

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 67-70, 72-75 and 77-90 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. In the instant case, the claims encompass a method of imaging and/or diagnosing cancer comprising contacting or administering a potent MN/CA IX specific inhibitor conjugated to a label or visualizing means, wherein the inhibitor is selected from the group consisting of organic heterocyclic and aromatic compounds and determined to be a potent inhibitor of MN/CA IX enzymatic activity in a screening assay comprising determining the inhibition constant of said compound, wherein if said inhibition constant is determined to be less than about 50 nanomolar, said inhibitor is determined to be a potent inhibitor of MN/CA IX ; and wherein potent inhibitor is determined to be an MN/CA IX specific inhibitor if it is a more potent inhibitor of MN/CA IX enzymatic activity than of the enzymatic activity of each of the carbonic anhydrases

in the group consisting of CA I, CA II and CA IV. Thus, the claims encompass a genus of compounds identified in a screening assay.

The specification teaches that CA IX specific inhibitors are preferably organic, more preferably aromatic or heterocyclic, and more preferably an aromatic sulfonamide or a heterocyclic sulfonamide, wherein the CA IX specific inhibitors are more potent inhibitors of CA IX enzymatic activity than of the enzymatic activity of a carbonic anhydrase selected from the group consisting of CA I, CA II and CA IV. For example, the specification teaches that exemplary and preferred aromatic sulfonamide or heterocyclic sulfonamide CA IX-specific inhibitors selected from group consisting of 91 compounds (see page 14 and Table 2 and Table 3). In particular, the specification teaches  $K_i$  values of said inhibitors for CA IX as compared to CA I, CA II and CA IV (Tables 2 and 3). Thus, while the specification reasonably conveys a number of compounds having a  $K_i$  value for CA IX of less than 50 nM, the specification does not appear to be commensurate in scope with the claimed invention since the specification appears to be silent on any compound possessing the claimed functional limitations identified in a screening assay. In other words, the claims encompass a genus of compounds defined only by their function wherein the relationship between the structural features of members of the genus and said function have not been defined. In the absence of such a relationship either disclosed in the as filed application or which would have been recognized based upon information readily available to one skilled in the art, the skilled artisan would not know how to make and use compounds that lack structural definition. The fact that one could have assayed a compound of interest using the claimed assays does not overcome this defect since one would have no knowledge beforehand as to whether or not any given compound (other than those that might be particularly disclosed in an application) would fall within the scope of what is claimed. It would require undue experimentation (be an undue burden) to randomly screen undefined compounds for the claimed activity.

Although the description does not provide working examples, the description teaches a method for measuring the biochemical and binding activity of the specific inhibitors and the person skilled in the art can understand how to use the screening method considering the common general knowledge.

To comply with the written description requirement of 35 U.S.C. § 112, first paragraph, a patent specification must describe the claimed invention in sufficient detail that one skilled in the art

can reasonably conclude that the inventor had possession of the claimed invention. An applicant shows possession of the claimed invention by describing the claimed invention Edith all of its limitations using such descriptive means as words, structures, figures, diagrams, and formulas that fully set forth may be shown in a variety of ways including description of an actual reduction to practice, or by showing that the invention was Already for patenting” such as by the use of drawings or structural chemical formulas that show that the invention was complete, or describing distinguishing identifying characteristics sufficient to show that the applicant was in Possession of the claimed invention.

As stated above the claimed invention is drawn to a method of imaging or diagnosing cancer using a compound identified by the screening method within the claim. However, no structural or specific functional characteristics of such an inhibitor is provided, nor is there any indication that the artisan actually implemented the method of so as to identify any inhibitor This situation is analogous to that of *Regents of the University of California v Eli Lilly*, 119 F.3d 1559, 43 USPQ2d 1398 (Fed. Cir. 1997). Because one skilled in the art would conclude that the inventors were not in possession of the claimed invention. The claim fails to comply with the written description requirement.

Therefore, No claims is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brandon J. Fetterolf, PhD whose telephone number is (571)-272-2919. The examiner can normally be reached on Monday through Friday from 7:30 to 4:30.

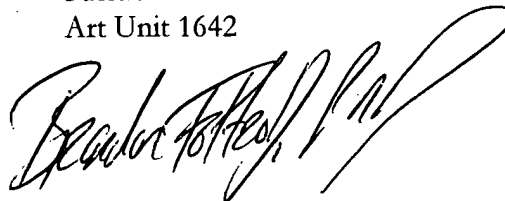
If attempts to reach the examiner by telephone are unsuccessful, the examiner’s supervisor, Larry Helms can be reached on 571-272-0832. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Brandon J Fetterolf, PhD  
Patent Examiner  
Art Unit 1642

A handwritten signature in black ink, appearing to read "Brandon J Fetterolf", with a large, sweeping flourish extending from the end of the name.

BF